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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|------------------|
| 09/913,629 | 05/15/2002 | Henning Schumacher | BKS-0002 | 2956 |
| 7590 | 08/10/2004 | | | |
| David A Cherry Woodcock Washburn Kurtz Mackiewicz & Norris 46th Floor One Liberty Place Philadelphia, PA 19103 | | | EXAMINER MCKANE, ELIZABETH L | |
| | | | ART UNIT 1744 | PAPER NUMBER |
| DATE MAILED: 08/10/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/913,629 | Applicant(s) SCHUMACHER, HENNING | |
| | Examiner Leigh McKane | Art Unit 1744 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 13 is/are rejected.
- 7) ☒ Claim(s) 4-12 and 14-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Specification

1. The amendment filed 6 July 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment specifically to claim 1, limiting the method for disinfecting to one *consisting of* contacting the lumina with the invert soap, is not supported by the specification. In fact, every formulation in the examples contains the invert soap in combination with other components. There is simply no evidence that the invert soap alone would disinfect and clean a confined lumina.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As set forth above, the amendment specifically to claim 1, limiting the method for disinfecting to one *consisting of* contacting the lumina with the invert soap, is not supported by the specification.

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing as it cannot be determined if the phrase “consisting of” is intended to limit the method steps or the composition.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishimura et al (JP 9-141271).

Nishimura et al teaches cleaning and sterilizing pipelines using didodecyl dimethylammonium chloride or dodecyl trimethylammonium chloride, among others. See English language machine translation, page 3.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishimura et al in view of Hall et al (U.S. Patent No. 5,547,990).

Nishimura et al teaches the use of dialkyl dimethylammonium halide invert soaps wherein the two alkyl groups are preferably C₅₋₁₈ and may be different. Nishimura et al is silent with respect to using isononyldecyldimethylammonium chloride as the invert soap. Hall et al teaches use of decylisononyldimethylammonium chloride as a hard surface disinfectant cleaner. See col.3, lines 3-5 and 65-66. As the disinfectant/cleaner of Hall is disclosed to be used in household, industrial, and institutional environments, it would have been obvious to use as the dialkyl dimethylammonium halide invert soap of Nishimura et al. With respect to contact temperature, it is generally recognized in the art of cleaning and disinfecting that an elevated temperature improves performance of both detergents and disinfectants. Thus, it would have been obvious to increase the temperature of the invert soap of Nishimura et al in order to improve cleaning and disinfecting of the pipeline.

Allowable Subject Matter

10. Claims 4-12 and 14-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

11. Applicant's arguments with respect to claims 1-3 and 13 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Venetsianos (WO 98/35933) teaches a mixture of benzyldimethyldodecyl ammonium chloride and benzyldimethyltetradecyl ammonium chloride as a disinfectant/cleaner.

Kioki et al (EP 639636) discloses a germicidal detergent containing a cationic germicide (dialkyldimethyl ammonium halide).

Malik (H269) teaches a disinfectant containing a germicidal quaternary ammonium halide.

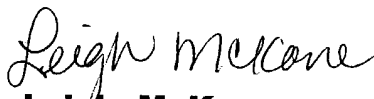
Iwai et al (abstract of "Microbial contamination and bactericidal activity of disinfectants for tracheal suction catheter") teaches the use of an invert soap (benzalkonium chloride) for the disinfection of tracheal catheters. Iwai et al does not teach using the invert soap for cleaning the catheter as well.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Wednesday (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1275. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Leigh McKane
Primary Examiner
Art Unit 1744

elm
9 August 2004